REMARKS

1. *Status of the Claims*

Claims 13-32 and 34 are pending. Claims 1-12 and 33 were previously cancelled. Claims 13-32 and 34 have been rejected.

2. *Claim Rejections - 35 U.S.C. § 103*

Claims 13-32 and 34 stand rejected under 35 U.S.C. §103 as allegedly obvious over Jansson et al., U.S. Pat. Application No. 1993 3009 (the '009 application) in view of Keyes, U.S. Pat. No. 4,713,335 (the '335 patent).

The Office Action asserts that the '009 application teaches a process for separating elements from the claimed biological material compound (i.e. fish or marine material) to obtain high yields of non-denatured protein, fats or lipids and intrinsically producing grax and trace elements when performing the '009 application's separation step whereas the '009 application's claimed process would also intrinsically produce the claimed composition comprising non-denatured protein and at least one of the group consisting of fat and lipid when such steps are performed as the steps of freezing and mechanically treating the biological material, i.e. mechanically treating by grinding. The Examiner also states the reference states one of ordinary skill would add pretreatment compounds such as solvents and/or enzymes because enzymes protect the lipids against oxidation within the process and the reference also states adding antioxidants wherein the process, (see e.g. page 3 and 4) at the claimed freezing temperature interval (i.e. freezing at –6 degree Celsius); subsequently heating the biological material to a temperature as not to denature the protein contained within the biological material (i.e. on page 9 of the '009 application's specification, it states that heating should be done at low temperatures not to denature the protein) and then separating and isolating high yields of lipids, fats or non-denatured protein whereas the '009 application's process intrinsically produce the claimed composition comprising non-denatured protein and at least one of the group consisting of fat and lipid. the '009 application's process is also done under a condition of a vacuum. The Examiner concedes that the '009

application does not expressly teach claims 30-31 wherein the denaturing temperature of the material is determined by visual observation (claim 30) and/or by viscosity measurements (claim 31).

The Examiner asserts that it would have been obvious to one of ordinary skill in the art at the time the invention was created to modify the '009 application's process to include visual observation to determine the denaturing temperature of a material because visual observation would be an intrinsic feature within the '009 application in monitoring the temperature within the process in order to not allow the protein to become denatured.

Furthermore, the Examiner asserts that the '335 patent teaches at column 5, lines 29-35, that viscosity measurements are used to monitor protein denaturation and/or determine the denaturing temperature within a material. The Examiner further asserts that it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the '009 application's process to include the disclosure of viscosity measurements used to monitor protein denaturation and/or determine the denaturing temperature within a material as taught by the '335 patent because the combined teachings would create a method of spearing elements from a material wherein the elements separated do not contain denatured proteins. The Examiner asserts that the adjustment of conventional working conditions (e.g. heating step is performed continuously and/or semi-continuously, the isolation step and the freezing rate and/or time period) is deemed merely a matter of judicial selection and routine optimization which is well within the purview of the skilled artisan. Moreover, the Examiner asserts, as the references indicate the various different steps used by the claimed method is result variable therefore they could be routinely optimized by one of ordinary skill in the art of practicing the invention disclosed by the references (e.g. the ordered pretreatment steps and the ordered mechanically treating steps occurs before said freezing step). The Examiner asserts that the selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results, and accordingly asserts that the invention as a whole is *prima facie* obvious.

Applicants respectfully traverse the rejection for the following reason.

The instant claim 13 recites a process comprising, in pertinent part, separating a composition from biological starting material, said separation being conformed to a known upper threshold temperature for the relevant organism in the starting material. The critical component of the instant invention is the step of determining a denaturing temperature *prior to* the heating step, and conforming the process of heating and separation accordingly, particularly since this temperature differs for each relevant organism and must be affirmatively determined by noting the first presence of protein agglomerates.

The '009 process does not contemplate this critical reaction condition, i.e. conforming reaction conditions to an upper threshold temperature which has been ascertained for the relevant organism/organisms in the starting material, maintaining a heating and separation steps at a temperature below an ascertained upper threshold temperature for the relevant biological starting material. The '009 process merely recommends keeping the temperature low to avoid as much as possible denaturing.

Nor is *conforming the process to a predetermined temperature applicable to the relevant organism/organisms* rendered intrinsic by the statement "in the case of low-temperature processes, the proteins are not denatured" (see page 9 of the '009 application). The '009 process entirely lacks any teaching, or even any suggestion of first determining the physical attributes of an oil, thereby determining a parameter vital to the claimed process, that of the denaturing temperature which dictates the subsequent step of heating to below the denaturing temperature. Page 9 of the '009 specification merely observes what is well known in the art, that low temperature processes produce undenatured proteins.

The fact is, by merely keeping the temperature low, there is no knowledge of, or control over, the possibility of inadvertently reaching and surpassing a denaturing temperature, particularly as the denaturing temperature differs from organism to organism.

Applicant respectfully points out that the Office has engaged in impermissible hindsight to support its arguments. In this regard, the Federal Circuit dictates that, "[i]t is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered

obvious . . . . This court has previously stated that '[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.'" *In re Fritch*, 972 F.2d 1260, 1266, 23 U.S.P.Q.2d 1780, 1784 (Fed. Cir. 1992). *See also Para-Ordinance Mfg., Inc. v. SGS Importers Int'l., Inc.*, 73 F.3d 1085, 1087, 37 U.S.P.Q.2d 1237, 1239 (Fed. Cir. 1995) (holding that "[o]bviousness may not be established using hindsight or in view of the teachings or suggestions of the inventor."); *Heidelberger Druckmaschinen AG v. Hantscho Commercial Prod., Inc.*, 21 F.3d 1068, 1072, 30 U.S.P.Q.2d 1377 (Fed. Cir. 1993) (holding that "[t]he motivation to combine references cannot come from the invention itself."); *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138, 227 U.S.P.Q. 543 (Fed. Cir. 1985) (holding that "the invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time").

As the instant application states at page 11 (WO0023545):

> The process according to the invention is characterised by the steps, being performed subsequently to the freezing and the division and diminution of the pieces of biological material, of thawing the frozen and processed material and isolating the oil at a temperature where the proteins do not start to denature, said denaturing temperature being determined by a visual inspection of the oil where the maximum temperature is the temperature where proteins in the oil start to form agglomerates visible as strings or a precipitate in the oil. Said maximum temperature is specific for the relevant organisms from which the oil is separated. As mentioned supra organisms from cold environments will normally have a lower maximum isolation temperature for the oil than organisms from a more temperate habitat.

In the absence of such contemplation, there simply was no suggestion or motivation to modify the '009 process with commonly known experimental procedures such as the viscosity measurements etc, as taught in the '335 patent. The '335 patent addresses temperatures which are *sufficient* to produce a denatured proteins (see for example, the Detailed Description in the '335 patent) not temperatures which at the cusp of starting the process of denaturing for the purpose of determining the temperature below which denaturing does not occur. In the '335 patent, the temperature sought is that at which denaturing is achieved and complete, the reverse of the object in

the instant invention – the '335 patent does not teach, nor does it suggest, the achieving of the temperature required by claim 13 of the instant invention.

Consequently, prior to Applicant's disclosure, there was no teaching or suggestion of the process of the instant invention. The cited references, when combined, do not teach or suggest all the claim limitations. See MPEP §2142. As discussed above, the '009 application's does not teach or suggest the claimed process. Therefore, the combination of the '009 application and the '335 patent do not teach or suggest all of the claims limitations of the new claims. Applicants respectfully assert therefore that claim 13 is novel and unobvious over the '009 applicant and the '335 patent. Since all the pending claims depend from claim 13, claims 13-32 and 34 are also patentable.

Applicants respectfully request withdrawal of the rejection.

CONCLUSION

Applicants respectfully contend that all conditions of patentability are met in the pending claims as amended. Allowance of the claims is thereby respectfully solicited.

If Examiner Randall believes it to be helpful, he is invited to contact the undersigned representative by telephone at (332) 408-2535.

Respectfully submitted,
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